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[54] **CONTAINER FOR USE WITH BLOOD WARMING APPARATUS**

[75] Inventors: **Randall Jay Sword**, Danvers; **John M. Collins**, Ipswich; **Jose Tadeo de Castro**, Newton, all of Mass.

[73] Assignee: **Baxter International Inc.**

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[51] **Int. Cl.**[6] **A61M 5/00**; H05B 1/02
[52] **U.S. Cl.** **604/113**; 604/403; 219/299
[58] **Field of Search** 604/415, 403, 604/407, 408, 113; 219/299, 296, 298, 301, 302, 305, 308, 309, 328, 497–499, 506

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Primary Examiner—John G. Weiss
Assistant Examiner—David J. Cho
Attorney, Agent, or Firm—Jeffrey C. Nichols; Francis C. Kowalik; Mark J. Buonaiuto

[57] **ABSTRACT**

A detachable assembly for an apparatus (**10**) for the controlled heating of fluid is provided. The apparatus (**10**) has a general elongated heating core (**16**) with a exterior surface (**36**) formed of a material having a high thermal conductivity and frustoconically shaped to slidingly receive an assembly (**14**) so that the assembly envelops the surface along at least a portion of the length of the core. The assembly (**14**) forms a sealed passageway (**46**) for generally unidirectional unrestricted sheet like flow upward along the core (**16**). A control system (**20**) selectively operates the heating core (**16**) so that the fluid, under varying flow rates, is warmed to a desired temperature without overheating, before the fluid flows from the passageway (**46**).

24 Claims, 5 Drawing Sheets

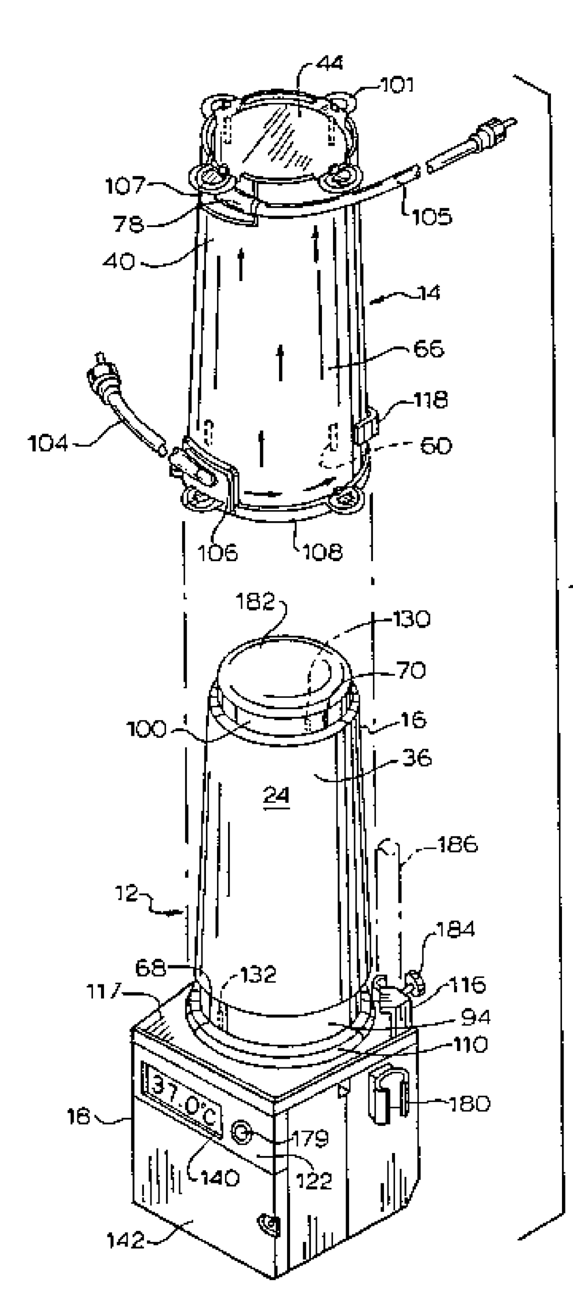

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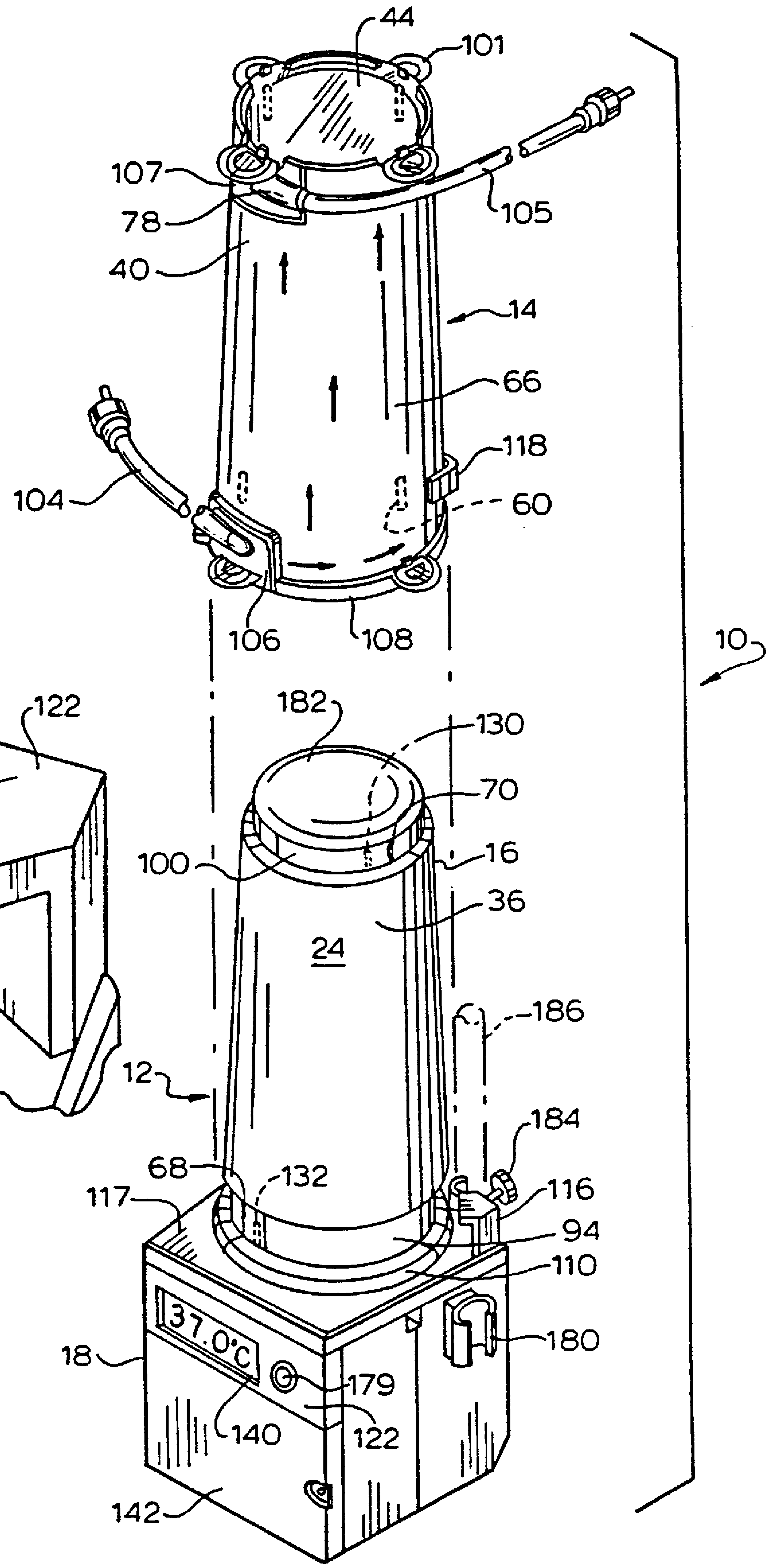
FIG.1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78
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108
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12
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94
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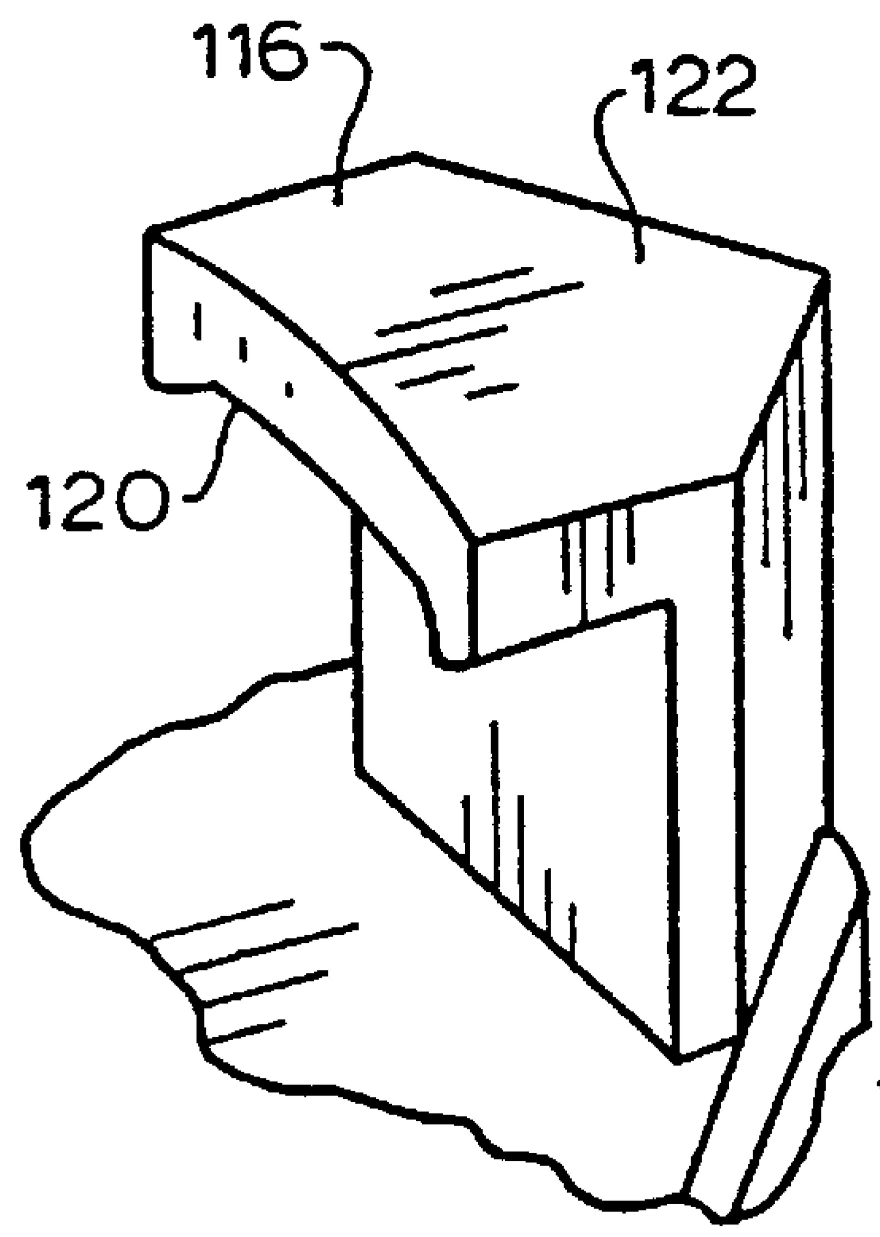
180
18
179
140
122
142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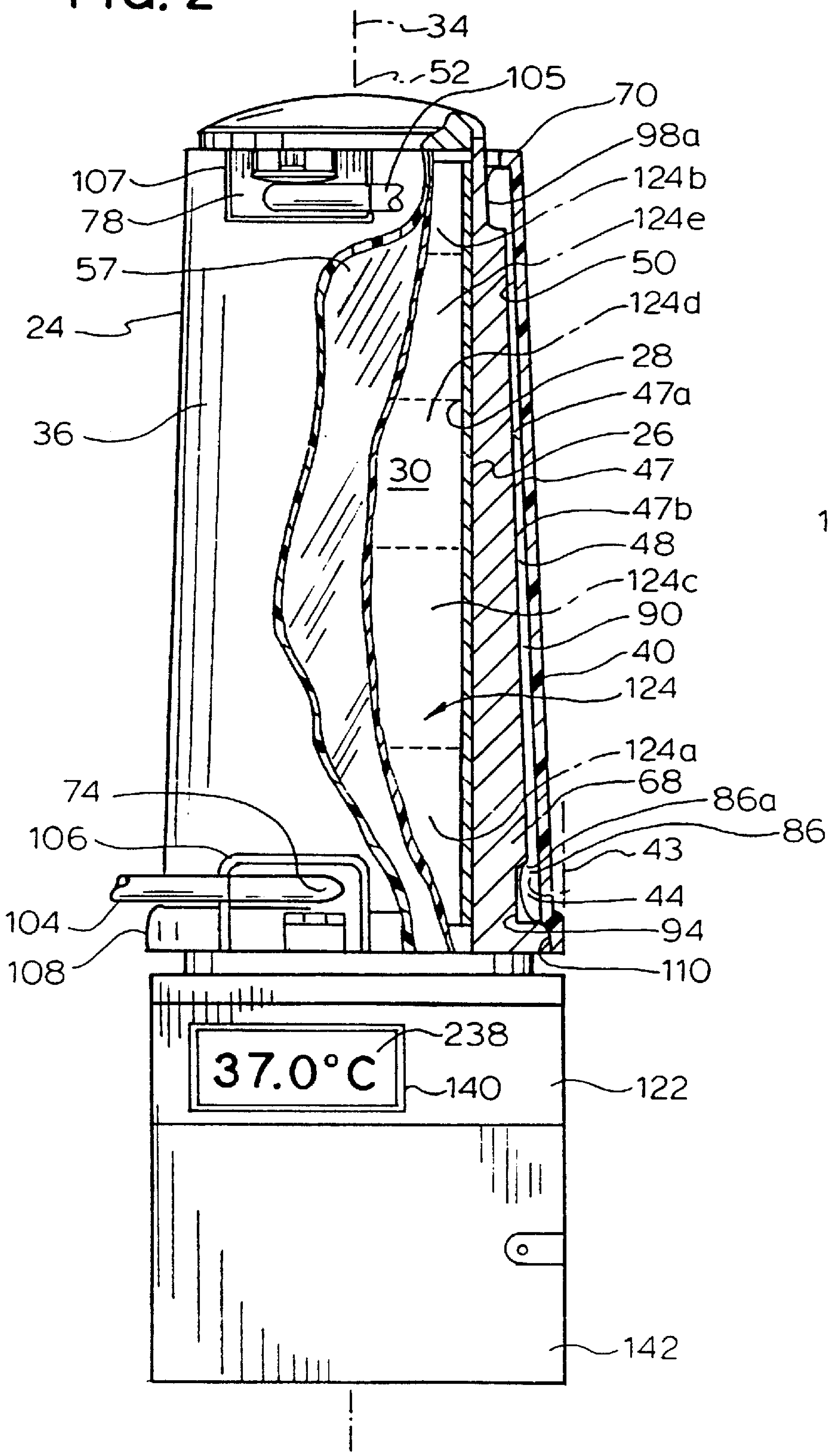
122
120

FIG.1a

FIG. 2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124a
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86a
86
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37.0°C
140
122
142

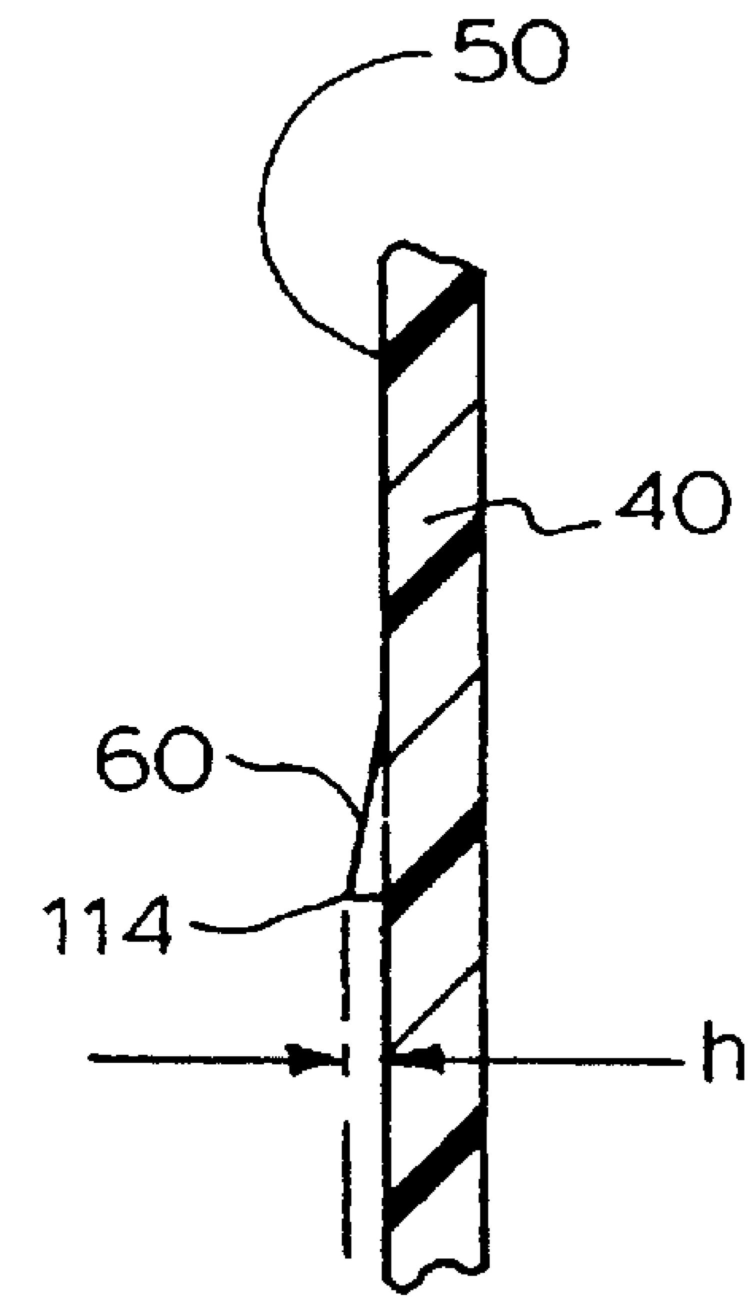
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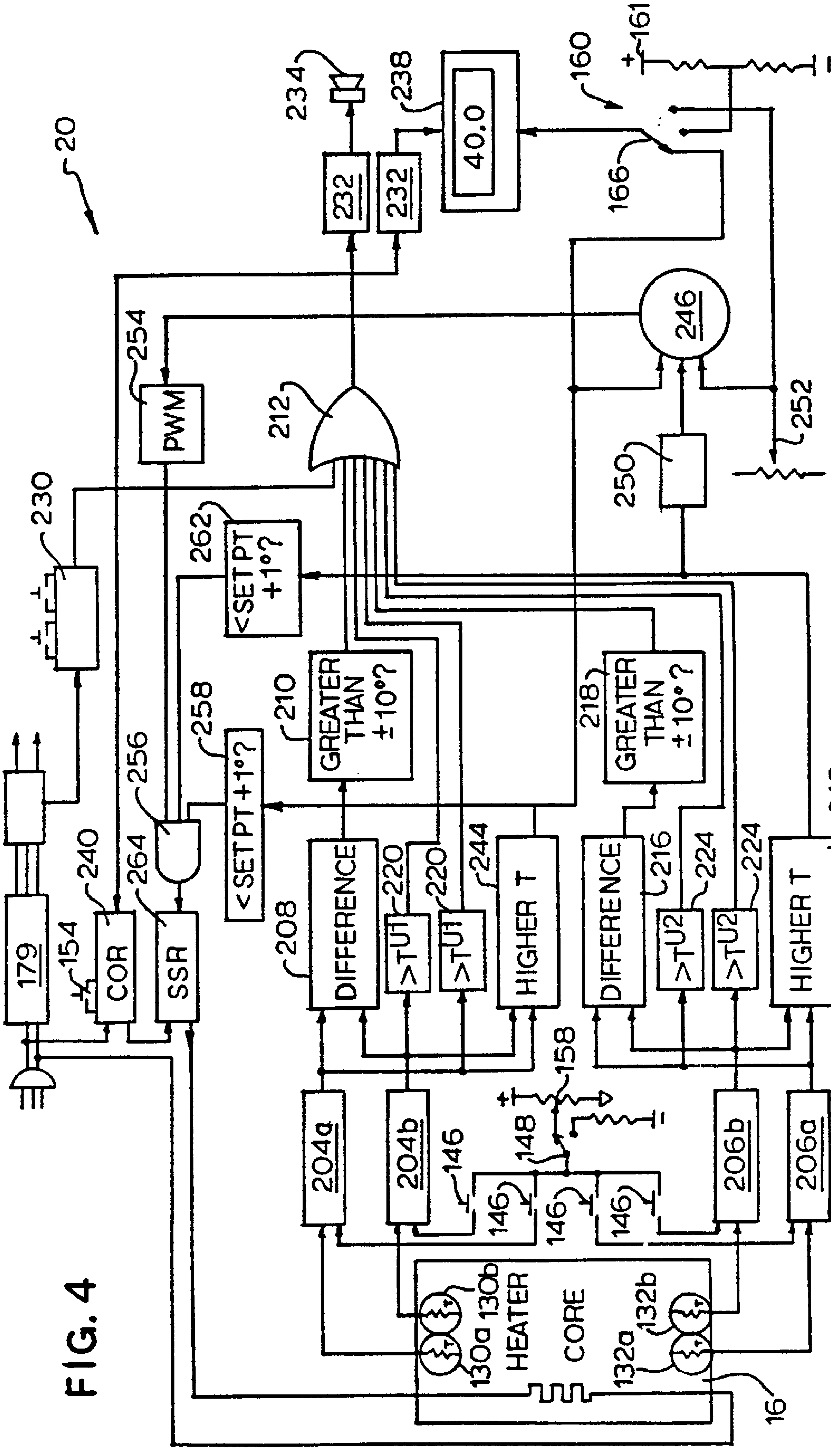
FIG. 3



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166
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244
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216
224
>TU2
>TU2
248
HIGHER T
158
148
146
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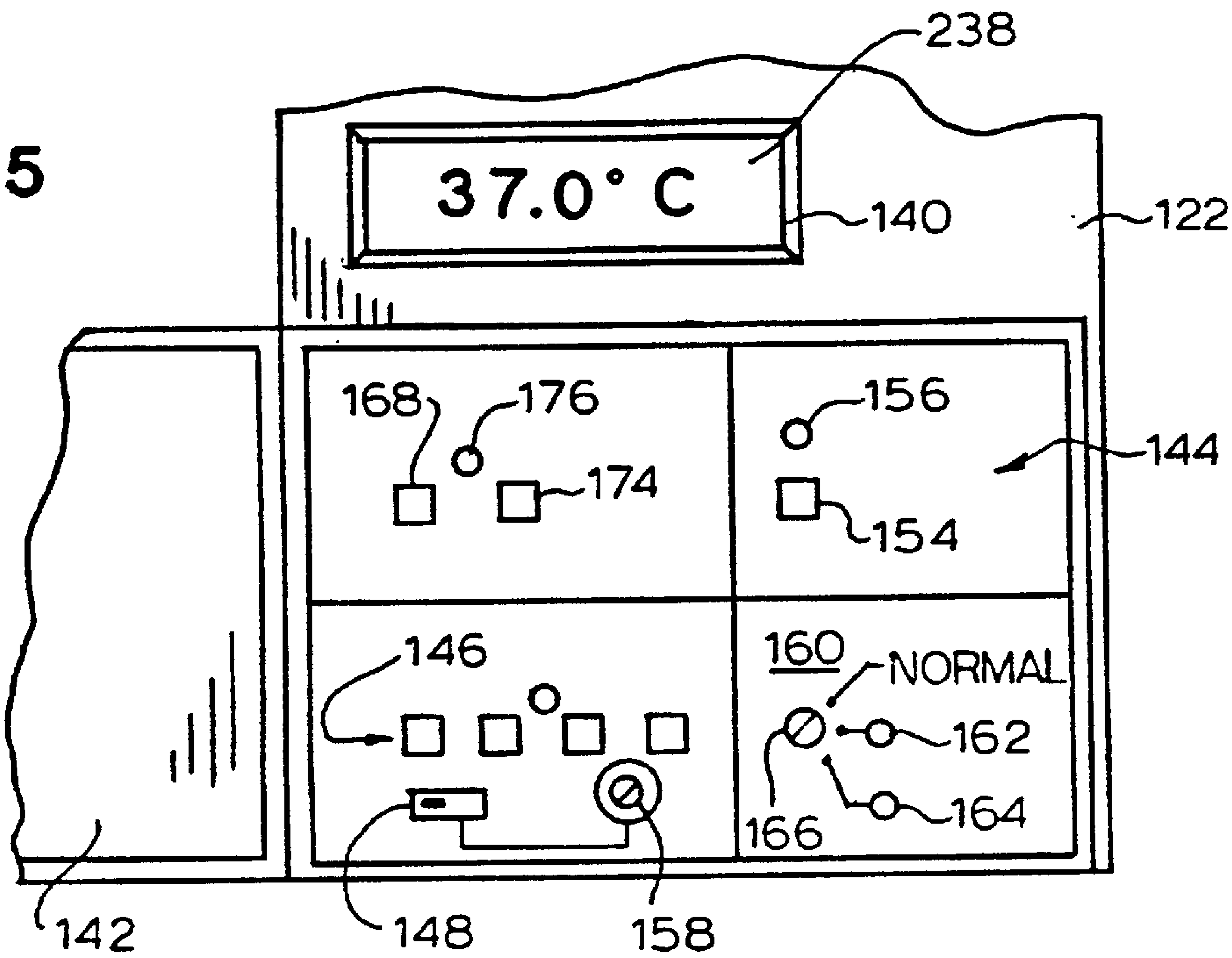
204b
206b
206a
130a
130b
HEATER
CORE
132a
132b
16

FIG. 4

FIG. 5


238
37.0° C
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NORMAL
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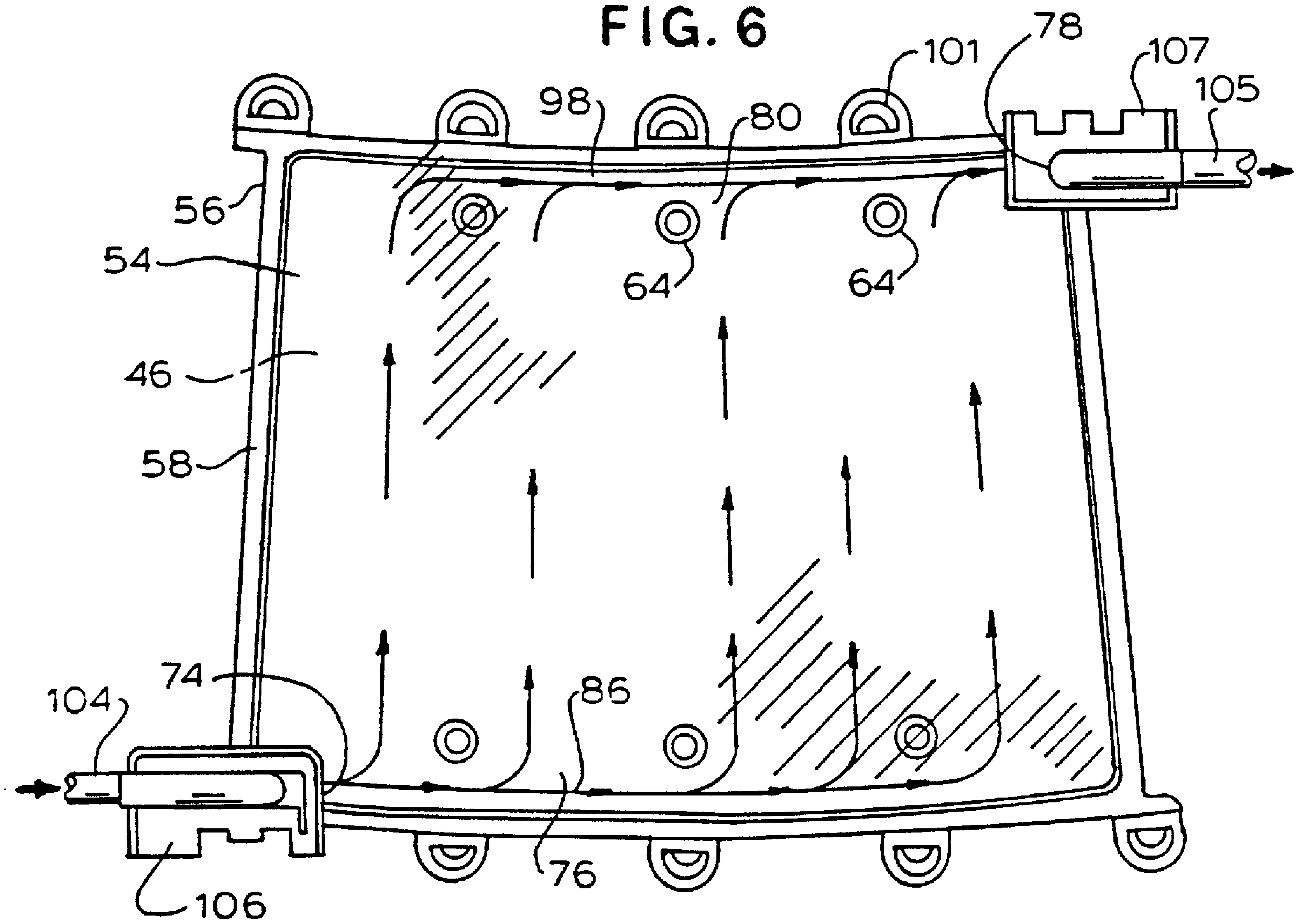
FIG. 6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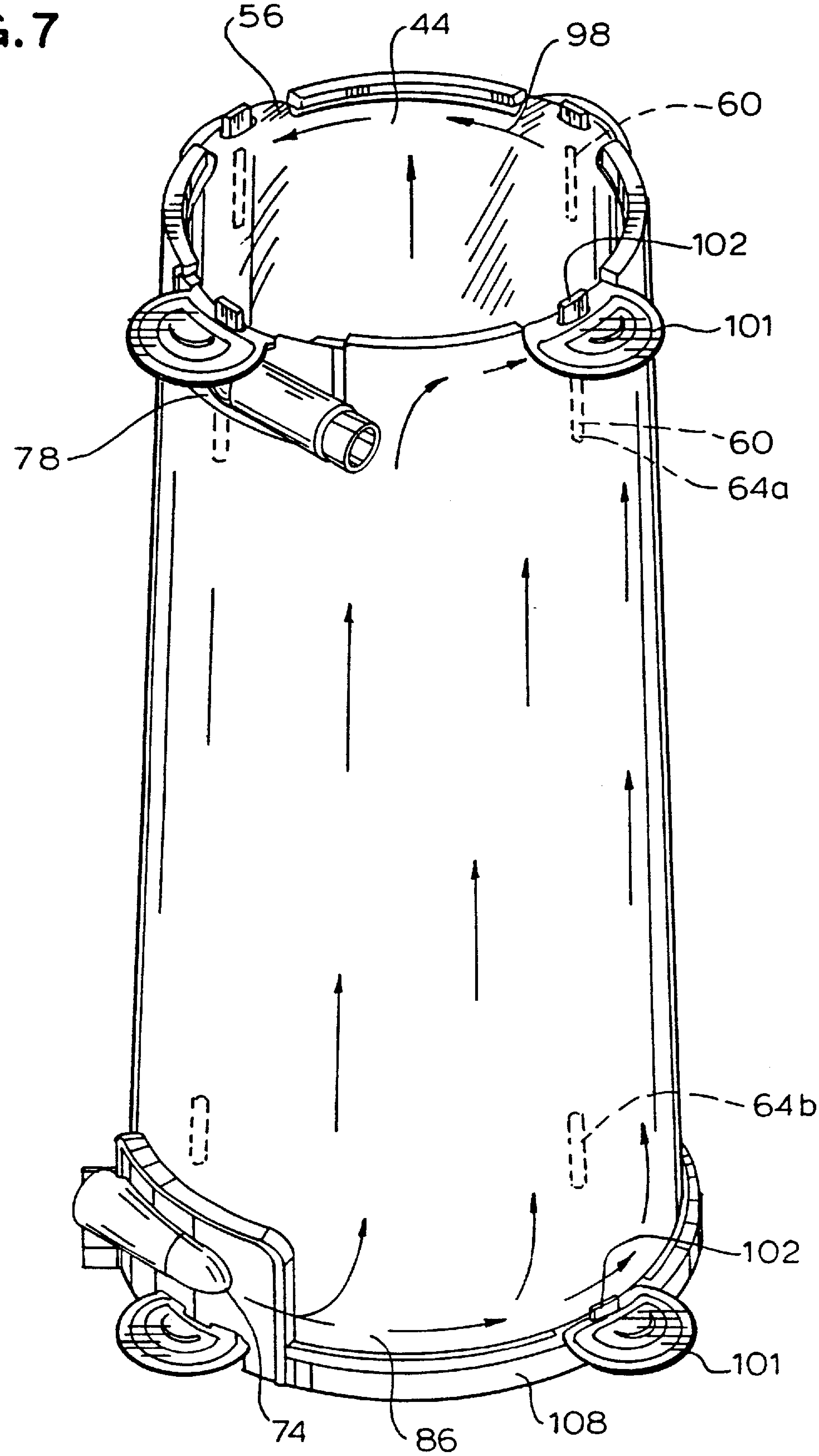
106

FIG. 7



CONTAINER FOR USE WITH BLOOD WARMING APPARATUS

BACKGROUND OF THE INVENTION

This invention is directed generally to an assembly forming a part of a fluid warming apparatus and providing a sealed passageway for the flow of fluid through the apparatus, more particularly, to such an assembly for an apparatus for warming parenteral fluid such as whole blood under controlled temperature conditions for transfusion procedures and the like.

Generally, whole blood is stored under refrigerated conditions at temperatures of approximately 4° C. to preserve the quality of the blood over extended periods of time. When the blood is to be infused into a patient, it is necessary that the blood be warmed to approximately 37° C., the temperature of the human body, to avoid possible hypothermia and the attendant risk of ventricular fibrillation and cardiac systole. On the other hand, if the blood temperature is permitted to rise excessively during the warming process, the blood may coagulate or deteriorate.

For many surgical procedures, the quantity of blood which must be warmed for use during the procedure may vary widely. If a quantity of blood is warmed which is sufficient for all foreseen conditions, all of the warmed blood may not be used, resulting in waste of the excess blood since it generally cannot be refrigerated again. Also, for accident victims or other emergency cases, the time required to warm a large quantity of blood for transfusion may become a critical factor.

To heat a large quantity of blood, the blood may be warmed as it flows from a storage assembly to the patient. However, the required flow rate differs among the many surgical conditions and procedures. Indeed during the same surgical procedure, the flow rate of the blood may vary widely. For example, during a procedure a patient may suddenly hemorrhage so that the flow of blood into the patient must be drastically increased. After the hemorrhaging is stopped, the flow of blood may drastically decrease.

It is therefore desirable to be able to controllably warm widely varying flow rates of a fluid, such as blood, with the fluid then delivered to the patient at a generally constant, desired temperature. Additionally if the fluid has an upper temperature limit the heating should be accomplished without overheating and deteriorating the fluid.

Furthermore it is desirable to provide an apparatus which may be operated without undue complexity and have a control system capable of accurately heating the fluid to a desired exit temperature.

It is also desirable to provide an apparatus for warming fluid which incorporates safety features to prevent excess warming due to a malfunction in the control system. In addition, the temperature to which the fluid is being warmed should be readily apparent to operators and other attendant personnel.

Moreover, it is desirable to provide a blood warming device which simplifies any setup and operational supervision in using the device, so that the potential for misuse is reduced.

Due to the danger of the transmission of diseases by injection of a contaminated fluid into the body, it is very important that any fluid warmer not allow contamination of the fluid. Frequently a blood warmer will incorporate an assembly such as a disposable element including a disposable tube or bag. The element completely contains the fluid as the fluid flows through the warmer.

It is desirable that any disposable element be easy to use with a "nondisposable" element of the warmer. Also if the disposable element is an element of the warmer generally described above, the element should be capable of handling varying flow rates without compromising the performance of the warmer. In addition any disposable element should have a small priming volume to reduce waste.

It is therefore an object of the present invention to provide an improved device or apparatus for fluid warming. A related object is to provide such an improved device which is particularly adapted to warm, cold parenteral fluids such as whole blood for use during surgical procedures.

It is a further object of the present invention to provide an improved fluid warming device for warming blood and other parenteral fluids to a generally constant temperature over a wide range of flow rates.

It is another object of the present invention to provide an improved fluid warming device which is convenient to operate and requires a minimal amount of operator supervision.

It is a still further object of the present invention to provide an improved fluid warming device which requires a minimum setup time. Furthermore it is desirable that the setup be achieved efficiently and safely.

A still further object of the present invention to provide an improved fluid warming device wherein the element of the device which comes into contact with the fluid during the warming process is disposable.

It is also an object of the present invention to provide a disposable element which is configured to integrate with the operational characteristics of a nondisposable element of the improved warming device. A related object is to provide such a disposable element which can accommodate widely varying flow rates without compromising the operational characteristics of the improved warming device.

It is a still further object of the present invention to provide a disposable element which uses a small priming volume. A related object is that the disposable element facilitate the correct operational attachment to the nondisposable element.

SUMMARY OF THE INVENTION

Accordingly an assembly forming a part of an apparatus for warming a flow of fluid is provided. The apparatus controllably warms the fluid over a wide range or varying flow rates. The preferably disposable assembly of the apparatus accommodates the varying flow rates.

The apparatus includes a heating base having a generally elongated heated mandrel defining an axis. At least a portion of the exterior surface of the mandrel is formed of a material having a high thermal conductivity and shaped to slidingly receive the assembly so that the mandrel heats fluid flowing through the assembly primarily by conduction. The conductive contact principally occurring between the mandrel and assembly.

The assembly includes an outer restraint. Attached to the restraint and disposed along an inner surface of the restraint is a bag. The bag has an inlet and an outlet, each of which are attached to connecting tubing. The bag preferably includes a pair of sidewalls attached to each other to form a sheet-like sealed passageway for the flow of the fluid between the inlet and outlet. The sheet-like passageway extends substantially about the circumference of the surface of the mandrel when the assembly is disposed about the mandrel.

The assembly and mandrel are configured to register the assembly relative to the mandrel so that the passageway through the bag is formed in a desired configuration. More particularly, the inner surface of the outer restraint and an outer surface of the mandrel bracket and constrain the sidewalls to establish a desirably configured, unrestricted sheet-like flow between an inlet and an outlet. The fluid is controllably warmed while flowing through the passageway.

In addition the assembly and mandrel are configured to form a desired flow rate distribution along the mandrel surface. The desired flow rate distribution interacts with the heat distribution along the mandrel surface to promote fluid heating without local hot spots, at which the temperature of the fluid may exceed an upper limit.

The apparatus also includes a system which controls the heat input into the flowing fluid. In dependence on temperature sensor inputs, the control system may vary the heat input to warm the fluid to a desired exit temperature without overheating any portion of the fluid. Preferably, the control system may also control the heat input to compensate for a varying flow rate.

Brief Description of the Drawings

FIG. **1** is a perspective exploded view with parts broken away of a preferred embodiment of the fluid warming apparatus including an assembly of the present invention;

FIG. **1***a* is a perspective view of a clamp forming a part of the fluid warming apparatus of FIG. **1**;

FIG. **2** is a side sectional view of the fluid warming apparatus of FIG. **1**;

FIG. **3** is an enlarged sectional view of standoff portions of the assembly forming a part of the fluid warming apparatus of FIG. **1**;

FIG. **4** is a functional block diagram of the electrical system forming a part of the apparatus of FIG. **1**;

FIG. **5** is a front elevational view of a control panel of the fluid warming apparatus of FIG. **1**;

FIG. **6** is a planar view of a cuff forming a part of the apparatus of FIG. **1** and shown in an unfolded position; and

FIG. **7** is a front elevational view of an attachable assembly forming a part of the apparatus of FIG. **1**.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. **1**, a preferred embodiment of a fluid warmer apparatus, including an assembly of the present invention, particularly configured for the warming of blood, is generally indicated at **10**. The warmer **10** includes a heating unit, generally indicated at **12**, which controllably warms fluid flowing through a sealed flow path formed by the attached assembly or assembly, generally indicated at **14**, which is preferably disposable and removable. The heating unit **12** has a heating core **16** connected to a base **18** which houses a portion of a control system **20**, diagramatically represented in FIG. **4**.

Referring also to FIG. **2**, the heating core **16** has a mandrel **24** composed of a material having high heat conductivity, such as aluminum or the like. Supplying heat to the mandrel **24** is a heater **26** formed as a sheet and in conductive contact with an interior surface **28** of the mandrel. The interior surface **28** is preferably constructed to form a cylindrical cavity **30** extending the height of the mandrel **24** and defining an axis **34** with the heater extending for at least a portion and preferably the majority of the height of the cavity.

An exterior surface **36** of the mandrel **24** is formed to facilitate the removable, enveloping positioning of the disposable assembly **14** about the mandrel. As will be discussed, the proper positioning of the assembly **14** relative to the mandrel **24** is important to obtain optimal performance of the warming apparatus **10**. The exterior surface **36** of the mandrel **24** and assembly **14** are formed in complementary frustoconical shapes. Preferably the surface **36** is configured to form a slight slope to a vertical reference **43**.

The Attachable Assembly

The assembly **14** includes an exterior restraint **40** and an interior bag or cuff **44** which forms a sealed passageway **46** (FIG. **6**) having a general sheet-like configuration, during the flow of fluid through the apparatus **10**. It is important to uniquely configure the passageway **46** so that as fluid flows through the warmer apparatus **10** the heat output of the heating unit **12** warms all of the fluid to the desired temperature without exceeding an upper temperature.

For the preferred embodiment of the warmer apparatus **10**, a sheet like flow with a generally constant thickness about the heating core is highly desirable. As such, correct relative positioning between the disposable element **14** and mandrel **24** is important. If the restraint is tilted relative to the mandrel **24** the thickness of portions of the passageway **46** are too thin. The flow may be restricted and slow. Similarly the thickness of portions of the passageway on an opposite side of the mandrel are too wide, and the flow may be too great.

It is therefore desirable to configure the restraint **40** and mandrel **24** to establish a boundary **47** for the passageway **46** whereby as fluid flows through the passageway, the passageway is formed with a uniform gap or thickness **48** about a majority of the surface area of the mandrel **24**. In one particular desired configuration the passageway **46** is formed with a uniform thickness over a majority of the length of the passageway outward along the mandrel **24**. An internal surface **50** of the restraint **40** forms an outer boundary **46***a* and mirrors the configuration of the exterior surface **36**. The exterior surface **36** forms an inner boundary **47***b,* and the exterior surface **36** and internal surface **50** form the passageway **46** with a uniform thickness when the disposable assembly **14** is juxtaposingly and properly positioned on the mandrel **24**. At least a portion and preferably a majority of the length of the passageway

In the preferred embodiment, a passageway **46** with a thickness of about 0.2 inches is established and such a passageway thickness produces good results. Other thickness will likely produce results sufficient to have the warming apparatus **10** operate within desired parameters.

To ease the effort required for proper positioning of the assembly **14**, it is preferred that the assembly **14** be allowed to fit about the mandrel **24** without regard to the relative angular orientation of the assembly and mandrel. In addition, rotation of the assembly relative to the mandrel **24** may be desired. Thus, horizontal cross sections of the internal surface **50** of the restraint **40** and exterior surface **36** of the mandrel **24** are generally circular and concentrically aligned with each other with the centers of the various cross sections defining an axis **52** over a majority of the length of the mandrel **24**. Preferably, to facilitate manufacturing, axis **52** and axis **34** are co-linear.

Referring to FIGS. **6** and **7**, the cuff **44** includes two sheets **54** juxtaposingly positioned and sealingly attached to each other about a peripheral edge **56** to form flexible sidewalls **57** for the sealed sheet-like passageway **46** for the flow of the fluid through the approaches. The cuff **44** is configured and curvingly folded to overlap or place lateral side edges **58** in an aligned abutting relationship and form a frustoconical shape to allow the cuff to be inserted within the restraint **40** and smoothly cover at least a portion of the interior surface **50** of the restraint **40**. Preferably, the cuff **44** smoothly and completely covers the interior surface **50** (FIG. **2**) along a substantial portion of the height of the restraint **40**.

Referring to FIGS. **2** and **6**, when fluid under pressure flows through the cuff **44**, the fluid forces the sheets **54** against the restraint **40** and mandrel **24** and the passageway **46** assumes the shape of the boundary **47**. To register and align the restraint **40** relative to the mandrel **24** to form passageway **46** with the uniform gap **48** axially along and circumferentially around the mandrel **24**, a series of stand-offs **60** (FIG. **3**) are formed to extend inward from the restraint. The standoffs **60** contact the exterior surface **36** of the mandrel **24** to support the assembly in the desired position relative to the mandrel.

As shown particularly in FIG. **7**, the 'pinching' of the passageway **46** and disturbance of the sheet like flow by the stand offs **60** is minimal. Preferably for at least a portion and more desirably for over half of the length of the passageway **46** outward along the mandrel **24**, the thickness of the passageway **46** within the cuff **44** is uniform circumferentially about the mandrel. Also, the opposing boundary surfaces of the mandrel and restraint **40** are entirely clear of any pinching obstructions over a substantial portion and preferably the majority of the length of the passageway **46**. Thus, fluid flowing through the passageway **46** flows in a generally sheet like configuration over a majority of the exterior surface area of the mandrel **24**.

In the preferred embodiment, the cuff **44** extends over the standoffs **60**. It may be anticipated that the contact between standoffs **60** and the mandrel **24** may damage the cuff **44**. Thus, the cuff **44** forms reinforcing dimples **64** which are aligned with the standoffs **60**. The dimples **64** are formed so that wear or puncture of the cuff **44** at the dimple does not rupture the passageway **46**. The dimples **64** are preferably formed by fusing the sheets **54** together to form a protective seal about the point of contact with the standoff **60**.

It is important that the restraint **40** be able to support the cuff **44** so that the flow of fluid under varying pressures and flow rates through the passageway **46** does not cause substantial variations in thickness of the passageway. In addition, the restraint **40** should protect the cuff **44**. Therefore, in the preferred embodiment, the restraint **40** is preferably a lightweight rigid shell **66**. It is also contemplated that the shell **66** may be pliable or flexible to reduce storage space. It is also envisioned that one of the sidewalls of the cuff **44** may form the restraint **40**.

The fluid flowing into the passageway **46** is directed to initially flow about a base **68** of the mandrel **24** and then flow upward in a sheet like configuration along the surface **36** to an upper end **70** of the mandrel. An inlet **74** for the fluid is formed in the cuff **44** at a lower end portion **76** and an outlet **78** is formed at an upper end portion **80**.

The mandrel **24** inputs heat, if necessary, to warm the fluid to the desired exit temperature. Especially if the fluid has an upper temperature limit, it is desirable that the fluid flow distribution be generally uniform within the passageway and about the mandrel **24**. The restraint **40**, cuff **44** and mandrel **24** cooperate so that fluid flowing into the passageway **46** first circumscribes the mandrel **24** before forming the sheet like flow which flows generally uniformly along the mandrel.

Particularly at high flow rates, the width or gap thickness of the passageway may hinder the initial distribution of the fluid about the mandrel **24** when the fluid initially flows into the inlet **74**. Therefore it is desirable to form an inlet manifold portion **86** of the passageway **46** which circumscribes the mandrel **24** along a lower edge **88** of the cuff **44**. The inlet manifold **86** is preferably formed by forming either the mandrel **24** or restraint **40** or both to form the inlet manifold **86** with a wider gap thickness than the thickness of the passageway along an intermediate portion or section **90** of the passageway **46**.

In the preferred embodiment, a radial groove **94** is formed in the mandrel **24** to circumscribe the base **68**, and the restraint **40** and groove form a boundary **86***a* of the inlet manifold **86**, as shown particularly in FIG. **1**. Alternately the restraint **40** could be configured with an outward extending radial ring portion (not shown). It is also contemplated that both the mandrel **24** and restraint **40** could be configured to form the boundary **86**a for manifold **86**.

Along similar reasoning, an outlet manifold portion **98** of the passageway is formed to circumscribe the mandrel **24** about the upper end **70** preferably by forming the mandrel with an upper radial groove **100**. The groove **100** and restraint **40** form a boundary **98***a* of the outlet manifold **98**. Alternate arrangements, as set forth above, are also contemplated.

To cooperate with the inlet manifold **86**, the inlet **74** is formed to direct the fluid along the length of the inlet manifold. Similarly the outlet **78** is formed so that fluid exiting from the passageway **46** flows out in directional alignment with the outlet manifold **98**. Therefore the inlet **74** and outlet **78** are formed to direct the fluid tangentially relative to the curved opposing surfaces of the restraint **40** and mandrel **24** and in directional alignment with the corresponding manifolds. As can be seen, it is preferred that the inlet **74** and outlet **78** direct the fluid generally normal to the axis **54** of the assembly.

The inlet **76** is connected to an inlet tube **104**, and the tube directs the inflowing fluid in the desired tangential and aligned direction. The peripheral edges **56** of the sheets **54** are sealingly bonded about the tube **104**. To provide strain relief, anchor and direct the tube **104** relative to the restraint **40**, the assembly **14** includes a bracket **106** which connects to the restraint. The bracket **106** also provides for passage of the tube **104** through the restraint **40** and into the gap **48** in the desired direction.

The outlet **78** is connected to an outlet tube **105** which is aligned with the outlet manifold **98**, and fluid flowing along the manifold **98** is directed into the tube. The peripheral edges **56** of the sheets **54** are sealingly bonded about the tube **105**. To provide strain relief, anchor and direct the tube **105** relative to the restraint **40**, the assembly **14** includes an upper bracket **107** which connects to the restraint. The bracket **107** also provides for passage of the tube **104** through the restraint **40** and into the gap **48** in the desired direction.

The cuff **44** may be formed with a series of outward ears **101** which attach to tabs **102** (formed along or adjacent to the edges of the restraint **40**) and maintain the cuff in a layer like configuration along the interior surface **50**.

When the assembly **14** is placed on the mandrel **24** and pressurized fluid is flowing through the passageway **46**, opposing hydraulic forces are applied by the sheets **54** on the mandrel and assembly. Due to the generally circular horizontal cross section of the restraint **40**, the forces on the restraint are directed generally radially outwardly and equally balanced about the circumference of the mandrel **24**. The hoop strength of the restraint **40** then counteracts the forces without requiring a latching mechanism or reinforced connecting points between the heating unit **12** and disposable assembly **14**.

Oppositely directed hydraulic forces force the sidewall **54** of the cuff **44** into contact with the mandrel **24** to establish good conductive contact between the cuff **44** and mandrel.

Also, to facilitate the proper positioning of the assembly **14** relative to the mandrel **24**, a lower apron **108** is fashioned on the shell **44** to abuttingly contact a radial boss **110** on the mandrel **24** and vertically align the shell with the mandrel. It is envisioned that the standoffs **60** principally performs the alignment of the assembly **14** relative to the base **1 8**, but the lower edge contact between apron **108** and boss **110** assists in preventing the assembly from being inadvertently jammed onto the mandrel **24** by the user.

Referring to FIGS. **3** and **7**, the standoffs **60** are preferably integrally formed with the restraint **40**, generally elongated and wedge shaped and form a tip **114** which contacts the mandrel **24**. The height "h" of the standoff **60** corresponds to the desired thickness of the gap **48** (FIG. **2**). The standoffs **60** are selectively placed so that when the restraint **40** is properly positioned relative to the mandrel **24**, the standoffs contact the mandrel and establish the gap. Preferably, the standoffs **64** are arranged to form two horizontally aligned sets, an upper set **64***a* close to an upper end of the mandrel **24**, and a lower set **64***b* close to a lower end of the mandrel. Each of the sets **64***a* and **64***b* are preferably equally angularly spaced about the circumference.

Referring to FIGS. **1** and **1***a,* to lock the assembly **14** on the heating unit **12** and yet allow for removal of the assembly, the heating unit includes a clamp **116** extending upward from an upper surface **117** of the base **18** in close proximity to the mandrel **24**. The clamp **116** coordinates with an outward extending ear **118** formed on the lower end of restraint **40**. To lock the cup **14** to the unit **12**, the disposable assembly **14** is slidingly placed about the mandrel **24** until the lower apron **108** contacts the boss **110** and the standoffs **60** contact the mandrel **24**. The cup **14** is then rotated until the ear **118** locks under the clamp **116**. Referring to FIG. **1***a,* to provide an indication of the locking as well as provide a small resistance to unlocking thereby reducing the chance of inadvertent unlocking, a notch **120** is formed along an underside of an upper element **122** of the clamp. The notch **120** is configured to seat the ear **118** when the assembly **14** is properly aligned with and locked to the base **18**.

The Heater Unit

Referring to FIGS. **2** and **7**, during operation, the fluid to be warmed flows through the inlet tube **104** and into the cuff **44** and upward along the heated mandrel **24**. Because the fluid will be coldest at the lower portion **46***a* of the passageway **46** and the potential for overheating the fluid greatest adjacent the outlet **78**, it is preferred that the heater **26** be configured to produce a heat output which varies and decreases along the length of the mandrel **24**. Referring to FIG. **2**, in the preferred embodiment, the heating sheet **26** is constructed so that the heat output of the heating sheet **26** is divided into five lateral bands **124**. Each band is of uniform heat output density, and the bands differ from each other in heat output density by a desired ratio. The lower lateral band **124***a* disposed along the lower end of the core **16** has a greater output than the upper lateral band **124***b* at the upper end with the intermediate bands **124***c*–**124***e* of an increasing heat output.

The heating sheet **26** may be configured with the heat output density of the upper band **124***b* approximately 20% of the heat output density of the lower band **124***a*. It has been found that forming the lower intermediate band **124***c* with a heat output density about 75% of the lower band, the intermediate band **124***d* with a heat output density about 50% of the lower band **124***a* and the intermediate band **124***e* with a heat output density of about 30% of the lower band produces good results. It is also anticipated that providing the heating core **16** with other distributions of heat outputs may also produce satisfactory results.

Referring also to FIG. **4**, to sense the temperature of the fluid so that the heating of the fluid can be controlled, the apparatus **10** includes at least one and preferably a plurality of temperature sensing devices **130** disposed in close proximity to the upper end of the mandrel **24**. Also the apparatus **10** includes at least one and a plurality of temperature sensing devices **132** disposed in close proximity to the lower end of the mandrel **24**. Preferably the devices **130** and **132** are disposed in the respective ends of the mandrel **24**. To provide good temperature sensing coverage and a safety feature, both the upper and lower sensing devices **130, 132** preferably include two (2) individual temperature sensing devices, with each of the devices in the pair disposed at opposite sides of the mandrel **24** or 180° apart. It is also preferred that the lower devices **132** are vertically aligned the upper devices **130**. To provide a safe and reliable system, the temperature sensing devices **130** and **132** are thermistors. Other types of temperature sensing devices may also be employed.

The Control System

Referring to FIG. **4**, the control system **20** is particularly suited to control the operation of the heater core **16** to safely heat the fluid, as the fluid flows through the disposable assembly **14** (FIG. **1**) under widely varying flow rate, to a desired temperature without overheating. Typical, inputs to the system **20** are the signal outputs from the upper temperature sensing devices **130***a* and **130***b* and the lower temperature sensing devices **132***a* and **132***b*. The signal outputs of upper temperature sensing devices **130***a* and **130***b* are amplified by circuits **204***a* and **204***b* respectively. Similarly the signal outputs of lower temperature sensing devices **132***a* and **132***b* are amplified by circuits **206***a* and **206***b*.

To verify that both of the upper temperature sensing devices **130***a* and **130***b* are functioning properly, one of an amplified output from each of the upper sensing devices is provided to a first comparator circuit **208**. The circuit **208** determines the difference in the two temperatures being sensed by the sensing devices **130***a* and **130***b*. The difference is then compared to a predetermined alarm value ΔT^1, preferably 10° C., by a circuit **210**. If the difference in the two temperatures being sensed by the sensing devices **130***a* and **130***b* is at least equal to or greater than ΔT^1, a likely malfunctioning upper temperature sensing device **130***a*, **130***b* is indicated and a first alarm signal is output to OR switch **212**.

To verify that both of the lower temperature sensing devices **132***a* and **132***b* are functioning properly, one of an amplified output from each of the lower sensing devices **132***a* and **132***b* is provided to a second comparator circuit **216**. The circuit **216** determines the difference in the two temperatures being sensed by the sensing devices **132***a* and **132***b*. The difference is then compared to a predetermined alarm value ΔT^2, preferably 10°, by a circuit **218**. If the difference in the two temperatures being sensed by the sensing devices **132**a and **132**b is at least equal to or greater than ΔT^2, a likely malfunctioning lower temperature sensing device **132**a or **132**b is indicated and a second alarm signal is output to OR switch **212**.

Referring briefly to FIG. **1**, to signal any overheating of the fluid as the fluid flows through the cup **14** (FIG. **1**), the control system **20** monitors the temperature of the mandrel **24** and alarms and shuts off the power to the heating core **16** when a predetermined upper limit temperature T^{U1} is at least equaled or exceeded. In particular, a second amplified output from each of the upper sensing devices **130**a and **130**b is provided to individual corresponding third comparator circuits **220**. Each of the third comparator circuits **220** compares the sensed input temperature to upper temperature limit T^{U1}. Should one of the third comparator circuits **220** determine that the sensed input temperature is greater than the upper alarm temp T^{U1}, a third alarm signal from that circuit is outputted to OR switch **212**. When the fluid being warmed is blood or the like, T^{U1} is preferably 42°.

Similarly, second amplified outputs from each of the lower sensing devices **132**a and **132**b are provided to corresponding individual fourth comparator circuits **224** which compare the input signal to a predetermined alarm temperature T^{U2}. T^{U2} preferably equals T^{U1}. If one of the circuits **224** determines that the higher temperature being sensed is at least equal to or higher than T^{U2}, that circuit outputs a fourth alarm signal to OR switch **212**.

Thus, it can be seen that the control system **20** uses the indicated temperatures provided by the temperature sensing devices to determine whether one of the upper sensing devices **130**a and **130**b is operating improperly and whether one of the lower sensing devices **132**a and **132**b is operating improperly, and produces an alarm signal if determination is made that a sensing device is not operating properly. Also the control system **20** determines whether any one of the upper sensing devices **130**a and **130**b or any one of the lower sensing devices **132**a and **132**b is sensing a temperature at least equal to or greater than the respective predetermined alarm temperatures, and producing an alarm signal if the alarm temperatures are equaled or exceeded.

The control system **20** also includes a voltage monitoring circuit **230** which monitors the electrical power being provided to the heating sheet **26** and the components making up the control system. The voltage monitor **230** outputs a fifth alarm signal to the OR switch **212** if a fault condition is determined.

If the OR switch **212** receives the first,second, third, fourth or fifth alarm signal from circuit **210**, circuit **218**, circuits **220**, circuits **224** or circuits **230**, respectively, a signal is transmitted to alarm circuits **232**. One of the alarm circuits **232** activates at least one audible alarm **234** which alerts health care providers to a fault condition. A second alarm circuit **232** may actuate a visual alarm provided by an action such as blinking the backlight or numerals of a display panel **238**. In addition to activating the alarm **234**, the output form the OR switch **212** may also be sent to activate a cut off relay **240** which switches off the power being supplied to the heating sheet **26** (FIG. **2**) at the heater core **16**. In the preferred embodiment, the cut off relay **240** may be switched back on when the alarm condition is no longer present, by turning the unit off and on.

Referring also to FIG. **1**, the control system **20** operatively controls the heating of the fluid in at least partial dependence on the temperatures sensed by at least one of the upper temperature sensing devices **130**a and **130**b and the lower temperature sensing devices **132**a and **132**b. The temperature of the fluid when the fluid flows from the apparatus **10** is typically highest when the fluid is adjacent to the upper end **70** of the mandrel **24**. Therefore, in the preferred embodiment, the control system **20** controls the heating of the core **16** in at least partial dependence on the highest temperature sensed by the upper temperature sensing devices **130**a and **130**b. In this operational process, an amplified output from each of the upper temperature sensors **130**a, **130**b is supplied to a fifth comparator circuit **244**. The fifth circuit **244** outputs the higher of the two temperature inputs to a first operational circuit **246**. The operational circuit **246** compares the input temperature to a set point temperature T^{SP} and averages the difference over a predetermined time period in determining the desired amount of power for the heater **26**. The set point temperature input is provided by an adjustable set point circuit **252** which is set to the desired temperature T^{SP} of the fluid exiting the apparatus **10**. The setting of the desired temperature T^{SP} is typically done during manufacture.

The output from the fifth circuit **244** is also sent to the display panel **236**, to be displayed to the users of the apparatus **10**.

The control system **20** is also preferably constructed to adjust the heat output of the heating unit **12** to compensate for sensed changes in the flow rate of the fluid through the apparatus **10**. Such adjustment is beneficial if the heat output of the heating unit **12** is primarily controlled by the sensed temperature of the fluid about the upper end **70**. For instance, the warming apparatus **10** may have achieved a steady state heat output and temperature control for a certain flow rate of fluid. Without any other control features, a sudden alteration in flow rate will not vary the heat output of the heating unit **12** until the upper sensors **130** detect a change in the temperature of the upper end **70**.

For example, a sudden increase in the flow rate of blood while maintaining a constant supply of heat will cause the temperature of the blood leaving the apparatus **10** to decrease. As set forth below, the heat output of the unit **12** will likely then increase, but the increase will likely not be timely or sufficient to warm blood which is at or approaching the outlet of the cuff **44**, to the desired temperature. Therefore, it is desirable to sense a changing flow rate as soon as possible, and in the preferred embodiment, at a location in close proximity to the inlet **74**.

In the preferred embodiment, the changes in the flow rate may be detected by monitoring the change in the temperature of the mandrel **24** in close proximity to the lower end **76** of the passageway **46** where the fluid initially flows into the cuff **44**. With the heating unit **12** providing a relatively constant heat output and the input fluid at lower temperature, substantial changes in the flow of the fluid will generally be reflected in changes in the temperature of the lower end of the mandrel **24** as sensed by the lower temperature sensing devices **132**a and **132**b. For example, a substantial increase in the flow of fluid into the passageway **46** will generally cause the lower end of the mandrel to cool off fairly rapidly. Thus, the heat output of the heater core **16** should be increased. Conversely, a substantial decrease in the flow of fluid into the passageway **46** will generally cause the lower end of the mandrel **24** to heat up fairly rapidly. Thus, the heat output of the heater core **16** should be decreased.

An output from each of the lower temperature sensors amplifying circuits **224** is provided to a sixth comparator circuit **248**. The output from the sixth comparator circuit **248** represents the higher temperature being sensed by the lower temperature sensing devices **132**a and **132**b, and is provided to a differential circuit **250** which generates the second input to the operational comparator circuit **246**. The second input generated by the differential circuit **250** varies at least in partial dependence on the rate of change in the temperatures being sensed by the lower temperature sensing devices **132***a* and **132***b*.

The operational circuit **246** sums the inputs from the differential circuit **250** and the power determination based on the average difference between the sensed temperature and the Set Point Temperature T^{SP} and outputs a signal to a power adjusting circuit **254**. Preferably the power adjusting circuit **254** is a pulse width modulator or the like, although other appropriate adjusting circuits are also contemplated. The output from the power adjusting circuit **254** is provided as a first input to junction **256**.

The control system **20** also includes a safety feature chiefly directed to prevent overheating of fluid leaving the apparatus **10** and the resulting activation of the alarm circuit **232**. The safety feature includes the process of shutting off the power to the heating core **16**, when any one of the upper temperature sensing devices **130***a* and **130***b* and lower temperature sensing devices **132***a* and **132***b* senses a trigger temperature T^{T}. The trigger temperature is preferably between the set point temperature T^{SP} and alarm temperatures T^{U1} and T^{U2}. In the preferred embodiment the trigger temperature T^{T} is set by the control system **20** to be equal to the set point temperature T^{SP} plus 1° C. The power is restored when the sensed temperature falls below the trigger temperature T^{T}. An output from the third comparator circuit **244** of the higher of the temperatures sensed by the upper temperature sensing devices **130***a* and **130***b*, is provided to a first set point comparator circuit **258** which compares the temperature to the trigger temperature T^{T}. If the temperature at least equals or exceeds the trigger temperature T^{T}, an indicative output is provided as a second input to the junction **256**.

Similarly, an output from the sixth comparator circuit **248**, which indicates the higher of the temperatures sensed by the lower temperature sensing devices **132***a* and **132***b*, is provided to a second set point comparator circuit **262** which compares the temperature to a second trigger temperature T^{T2}, which is preferably the same as the first trigger temperature (although it is contemplated that the trigger temperatures may vary). If the indicated temperature at least equals or exceeds the second trigger temperature, an indicative output is provided as a third input to the junction **256**.

Unless the junction **256** receives the output from the first set point comparator circuit **258** or the output from the second set point indicator circuit **262**, the junction **254** transmits the first input, supplied by the power adjusting circuit **254**, onward to a switching circuit **264**, preferably a zero crossing solid state relay or the like. The switching circuit **264** selectively controls the power being provided to the heater **26**, so that sufficient heat is being outputted by the heater to warm the fluid flowing through the apparatus, to the desired exit or set point temperature.

However, an output from either of the set point comparator circuits **258**, **262** overrides the output from the power adjusting output **254** to cause the switching circuit **264** to shut off power to the heater **26**. The control of the power adjusting circuit **254** is restored when the highest sensed temperature falls below both of the trigger temperatures T^{T1}, T^{T2}.

Although in the preferred embodiment, the control logic of the warmer **10** is achieved by using a novel arrangement of circuit elements, other methods of controlling the heater **26** output to controllably heat fluid are also contemplated. It is envisioned that control may also be achieved by using a microprocessor and appropriate programming. Such programming may be placed in volatile or nonvolatile memory or combinations of multiple types of memory. In addition portions of the program may be contained in different memory units some of which may be removable to allow remote programming or easy configuration of the operating characteristics of the warmer **10** for different fluids.

The Control Panel

Referring to FIGS. **1** and **2**, the base **18** is formed in a general configuration of a cube. A forward face **122** of the base **18** forms a viewing opening **140** through which the display **238** is visible. Forming a part of the base **18** and attached to the forward face **140** by a hinge, is a latch door **142**. Referring to FIG. **5** in conjunction with FIG. **4**, the latch door **142** provides a protective covering to a control panel generally indicated at **144**. The control panel **144** provides a simplified means for the technician to conduct tests on the control system **20** of the apparatus **10**. Included in the control panel are button switches **146** which form a test for the upper temperature sensors **130***a* and **130***b* and the lower temperature sensors **132***a* and **132***b*. Affiliated with the button switches **146** is a switch **148** for selectively choosing one of a plurality of test conditions. Pressing of one of the button switches **146** creates a simulated fault condition in the respective temperature-sensing device and results in tripping the alarm circuit **232** or an alarm condition. In addition, a light **150** illuminates to indicate when a button switch **146** has been depressed.

The specific test condition is dependent on the position of the switch **148**. In a first position, pressing one of the button switches **146** simulates a failed sensor, thereby causing the alarm circuit **232** to activate, activating the cut off relay **240**. The cut off relay **240** may be reset by a reset switch **154**. When the reset switch **154** is depressed an associated LED indicator light **156** is illuminated, the relay **240** is reset and the indicator light **150** is extinguished.

By setting the switch **148** in a second position and depressing one of the switches **146**, an over temperature condition may be simulated using a potentiometer **158**. As the potentiometer is adjusted, the technician may view the display **238**, and if the control system **20** is working properly, the alarm circuit **232** activates when the alarm temperature, as shown in the display, is exceeded. The cut off relay is activated and the indicator light **150** also lights. Pressing the reset switch **154** resets the circuitry .

In addition, the control system **20** includes means **160** for determining whether the display **238** is properly calibrated. More particularly, the means for verifying the calibration of the display **238** is a predetermined reference voltage circuit **161** with an associated light **162**. The temperature set point calibration means also includes the adjustable set point circuit **152** and an associated light **164**.

To set the warming apparatus **10** in the proper mode for either normal operation; display calibration, or temperature set-point adjustment, a three position rotary switch **166** is preferably used. To perform one of the tests, the mode selector switch **166** is rotated to the proper position and the technician looks at the temperature shown in the display. The light **162** or **164** will illuminate to also indicate which test is being run. If the display calibration test is being run the display should indicate a temperature corresponding to the predetermined test voltage. For example, the test voltage may correspond to 50° C., therefore, the display, if properly functioning, should show that temperature. If the set point test is being run, the display should indicate the temperature of the set point. The third position of the switch **166** is to place the heating unit **12** in normal operation, and both of the indicator lights **152, 154** are no longer illuminated.

The control panel **144** also includes a switch **168** and associated for testing the control circuitry and a switch **174** for testing the circuitry which adjusts the heat output i dependence on the rate of change of the lower sensors light **170**. Depressing either of these switches **168, 174**, also illuminates a corresponding light **176**, activates the alarm circuit **232** and shuts off the cut off relay **240**. The alarm **232** and cut off relay **240** may be reset and the illuminated light **176** extinguished by pressing the reset switch **154**.

In summary, various alarm conditions and the visual display may be checked by a technician through utilizing test switches. In performing each test, the corresponding indicating light is illuminated. Thus, when all the tests are completed and the circuitry appropriately reset, all the lights will be out.

After the testing is completed, the door **142** is closed and locked to prevent access by later users of the apparatus **10**. To help insure the proper operation of the apparatus **10**, the later user is limited to an on off switch **179** (FIG. **1**). Should a "nuisance" alarm condition occur in later use, the control system **20** may be reset by turning the apparatus **10** off and back on with the on-off switch **179**. Continued alarm indications after such a maneuver will likely indicate a malfunctioning apparatus **10**.

Referring back to FIG. **1**, the preferred embodiment of the base **18** also includes a friction-fit holder **180** for retaining a bubble trap(not shown) which is commonly used while administering blood or the like to a patient. The apparatus **10** also includes a cover **182** which fits about a top end of the heating core **16** for environmental protection.

For mounting, the apparatus **10** includes a clamp **184**, attached to the base **18**, which clamps the apparatus to a rod **186**. The clamp **180** also allows the apparatus **10** to be easily removed from the rod **186**. The rod **186** is usually found in a vertical orientation, but due to the apparatus's **10** operating characteristics, the apparatus may be operated in any orientation

In operation, the assembly **14** is slidably inserted over the mandrel **24** until the standoffs **60** contact the exterior surface **36** of the mandrel **24**. The contact between the standoffs **60** and exterior surface **36** center the restraint **40** relative to the surface **36**, establishing the passageway **46** with the uniform gap or thickness **48** (FIG. **2**) between the restraint and surface over the majority of surface area of the surface **36**. Also, the wider spacing between the restraint **40** and mandrel **24** at the lower radial groove **94** and the upper groove **100** form the boundary **86***a* of the inlet manifold portion **86** and the boundary **98***a* of the outlet manifold portion **98** of he passageway, respectively.

The lower apron **108** of the restraint **40** contacts the boss **110** on the mandrel. The assembly **14** may then be rotated relative to the heating unit **12** until the ear **118** snaps under the notch **120** (FIG. **1***a*) formed in the clamp **116**.

Fluid then flows into the cuff **44** by flowing through the inlet tube **104**. The tube **104** directs the fluid so that when the fluid enters the cuff **44**, the fluid is directed tangentially relative to the surface **36** of the mandrel **24** and also along the length of the manifold **86**. As the fluid flows into the passageway **46**, air is purged from the passageway, priming the apparatus **10**.

As fluid first enters the passageway **46**, the fluid fills the inlet manifold **86** circumscribing the mandrel **24**. The fluid then flows along the length of the mandrel **24** in a sheet-like flow. The fluid is then heated as the fluid flows in a generally unidirectional unrestricted vertical flow upward about the heater core **16**. When the apparatus **10** is activated, the control system **20** (FIG. **4**) controls the heat input into the flowing fluid so that the fluid is warmed to a desired temperature before the fluid flows from the passageway **46**.

The pressure of the fluid forms an inward radial force pressing the inner sidewall **57** of the side sheets **54** against the mandrel **24** and a counteracting outward radial force to press the outer sidewall **57** of the sheets **54** against the restraint **40**. The outward force is evenly distributed about the circumference of the restraint **40**, to promote the centering of the restraint on the mandrel **24**, and the gap **48** and passageway **46** are of generally constant thickness about the heating core **16**. The constant thickness of the passageway **46** promotes even heating of the fluid to prevent hot spots. Also, the pressing of the inner of the side sheets **54** against the heater core **16** facilitates heat transfer to the fluid.

The heated fluid is then collected in the outlet manifold **98** and exits the manifold via the outlet tube **105** in a direction aligned with the length of the manifold and generally tangential to the surface **36** of the mandrel **24**.

If the upper tube **80** is connected to an administration set which includes a bubble trap (not shown), the bubble trap can be attached to the clamp **180**.

After the medical procedure has reached a point where warmed blood is no longer needed, the heating unit **12** is shut off, and the assembly **14** is then rotated relative to the heating unit **12** until the ear **118** snaps out from under the notch **120** formed in the clamp **116**. The assembly **14** may then be slidably removed in an upward direction from the mandrel **24**, and disposed of in the proper manner.

As can be seen from the above operational description, the set up and operation of the warming apparatus **10** is fairly simple and the amount of operational supervision is low. In general terms, the set up includes a sliding snap fit of the disposable assembly **14** onto the heating unit **12**. Depressing the on off switch **179** activates the assembly **10**. Supervision includes observing for alarms and monitoring the displayed temperature.

While a particular embodiment of the blood warming apparatus has been shown and described, it will be appreciated by those skilled in the art that changes and modifications may be made thereto without departing from the invention in its broader aspects and as set forth in the following claims.

What is claimed is:

1. An assembly for placing a flow of fluid in thermal contact with a warming apparatus, the warming apparatus having a heated elongated mandrel with a generally smooth, frustoconical outer surface defining a central axis, the mandrel defining a radial groove on a lower portion of the mandrel, the assembly comprising:

an outer restraint adapted to slidingly fit about at least a portion of the length of the mandrel, the restraint having two ends and an inner surface, the inner surface defining a longitudinal axis, the inner surface and outer surface of the mandrel forming a boundary for a passageway for the flow of the fluid through the assembly, the radial groove and restraint forming a boundary for an inlet manifold portion of the passageway, the inlet manifold being proximate one end of the assembly;

first means for directing an inlet flow of fluid into and along the inlet manifold; and a sterilized bag including an inlet and an outlet and two sidewalls attached to each other to form and seal the passageway, the bag being attached to the restraint and disposed generally along the inner surface, the inner surface being shaped so that when the restraint is disposed about the mandrel, when fluid flows through the passageway, the inner surface and outer surface of the mandrel support a generally uniform separation of the sidewalls without forming pinch points over at least a portion of the length of the passageway longitudinally along the mandrel.

2. The assembly of claim **1** including a sterilized bag including an inlet and an outlet and two sidewalls, the sidewalls being attached to each other to form a sealed passageway for the fluid from the inlet to the outlet, the bag being attached to the outer restraint and disposed generally within the inner surface so that the inlet is proximate one of the end of the restraint and the outlet is proximate the other end of the restraint.

3. The assembly of claim **2** wherein the inner surface of the restraint is shaped so that when the restraint is disposed about the mandrel and the fluid flows from the inlet to the outlet, the inner surface and outer surface of the mandrel maintain a generally uniform separation of the sidewalls without forming pinch points over the majority of the length of the passageway.

4. The assembly of claim **1** wherein the restraint is shaped so that over a majority of the surface area of the mandrel, the fluid flows in a generally uninterrupted sheet like configuration within the passageway from the inlet manifold along the length of the mandrel.

5. The assembly of claim **1** wherein the first directing means is configured to direct an inflow of blood into the inlet manifold in a direction tangential to the exterior of the mandrel and generally normal relative to a longitudinal axis defined by the mandrel.

6. The assembly of claim **1** wherein the first directing means includes a bracket attached to the restraint.

7. The assembly of claim **1** wherein the inner surface is generally frustoconically shaped.

8. The assembly of claim **1** wherein the assembly is configured to engage the mandrel and dispose the assembly in the desired relative position.

9. The apparatus of claim **1** wherein the assembly includes means attached to the restraint for engaging the mandrel and establishing the desired relative position.

10. The assembly of claim **1** wherein the restraint includes a rigid shell.

11. The assembly of claim **1** wherein the assembly and the exterior surface of the mandrel are configured to form the passageway so that as fluid flows through the passageway the fluid flow forms a generally uninterrupted sheet like configuration over a majority of the surface area of the mandrel when the assembly is disposed in a desired position relative to the mandrel.

12. The assembly of claim **11** wherein the passageway is generally of a constant thickness.

13. The assembly of claim **1** wherein the restraint forms standoffs disposed generally proximate the inlet and outlet of the passageway, the standoffs configured to engage the mandrel and dispose the restraint in a desired angular position relative to the mandrel so that the passageway is of generally constant thickness circumferentially about the mandrel.

14. The assembly of claim **1** wherein the mandrel defines a second radial groove, the restraint and radial groove defining the boundary of an outlet manifold portion of the passageway, the assembly including second means for directing a flow of fluid from the outlet manifold in a direction generally aligned with the outlet manifold.

15. The apparatus of claim **14** wherein the assembly includes a flexible sidewall forming an interior wall for the passageway.

16. The apparatus of claim **15** wherein the assembly includes a bag sealingly forming the passageway.

17. The assembly of claim **15** wherein the restraint is a rigid shell.

18. The assembly of claim **14** wherein the second directing means is configured to direct an outflow of blood out of the outlet manifold in a direction tangential to the exterior of the mandrel and generally normal relative to a longitudinal axis define by the mandrel.

19. An assembly for placing a flow of fluid in thermal contact with a warming apparatus, the warming apparatus having a heated elongated mandrel with a generally smooth, frustoconical outer surface defining a central axis, the mandrel defining a first radial groove on a lower portion of the mandrel and a second radial groove on an upper portion of the mandrel, the assembly comprising:

an outer restraint adapted to slidingly fit about at least a portion of the length of the mandrel, the restraint having two ends and an inner surface, the inner surface defining a longitudinal axis, the inner surface and outer surface of the mandrel forming a boundary for a passageway for the flow of the fluid through the assembly, the first radial groove and restraint forming a boundary for an inlet manifold portion of the passageway, the inlet manifold being proximate one end of the assembly; and

first means for directing an inlet flow of fluid into and along the inlet manifold; and

the restraint and second radial groove defining the boundary of an outlet manifold portion of the passageway and second means for directing a flow of fluid from the outlet manifold in a direction generally aligned with the outlet manifold; and

a sterilized bag including an inlet and an outlet and two sidewalls attached to each other to form and seal the passageway, the bag being attached to the restraint and disposed generally along the inner surface.

20. An assembly for placing a flow of fluid in thermal contact with a warming apparatus, the warming apparatus having a heated elongated mandrel with a generally smooth, frustoconical outer surface extending from a first end to a second the end, the first end having a smaller radius than the second end, the mandrel defining a central axis, the mandrel forming a first radial groove formed on a portion of the first end of the mandrel, and extending about said axis generally normal to said axis and a second radial groove on a portion of the second end of the mandrel, the second groove extending about said axis generally normal to said axis, the assembly comprising:

an outer restraint adapted to slidingly fit about at least a portion of the length of the mandrel, the restraint having a first end and a second end corresponding to the first end and second end of the mandrel and an inner surface, the inner surface defining a longitudinal axis, when the restraint fitted about the portion of the length, the inner surface and outer surface of the mandrel forming a boundary for a passageway for the flow of the fluid through the assembly with the first radial groove and restraint forming a boundary for an outlet manifold portion of the passageway;

an outlet attached to the restraint proximate the first end of the restraint and arranged relative to the restraint to direct an outlet flow of the fluid from the outlet manifold in general radial direction generally aligned with the outlet manifold; and

an inlet attached to the restraint proximate the second end of the restraint and arranged relative to the restraint to direct an inlet flow of the fluid into the passageway in a generally radial direction; and

a sterilized bag including an inlet and an outlet and two sidewalls attached to each other to form and seal the passageway the bag being attached to the restraint and disposed generally along the inner surface.

21. An assembly for placing a flow of fluid in thermal contact with a warming apparatus, the warming apparatus having a heated elongated mandrel with a generally smooth, frustoconical outer surface extending from a first end to a second the end, the first end having a smaller radius than the second end, the mandrel defining a central axis, the assembly comprising:

an outer restraint adapted to slidingly fit about at least a portion of the length of the mandrel, the restraint having two ends and an inner surface, the inner surface defining a longitudinal axis, the inner surface and outer surface of the mandrel forming a boundary for a passageway for the flow of the fluid through the assembly, the restraint including a plurality of standoffs to position the restraint relative to the mandrel;

an inlet to the passageway attached tot he restraint at a first end of the restraint and the outlet attached to an opposite end of the restraint;

the inner surface being configured in a generally smooth frustoconical configuration such that the passageway provides for flow of fluid in a generally sheetlike configuration extending from said first end to said opposite end; and

a sterilized bag including an inlet and an outlet and two sidewalls attached to each other to form and seal the passageway, the bag being attached to the restraint and disposed generally along the inner surface.

22. The assembly of claim **21** wherein the inner surface of the restraint forms the passageway with a generally uniform thickness substantially free of pinchpoints along a majority of the length of the passageway.

23. The assembly of claim **1** wherein the restraint is generally flexible.

24. The assembly of claim **14** wherein the restraint is generally flexible.

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